



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|---|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/522,457 | 01/21/2005 | Eric Ferrandis | 427.094 | 5578 |
| 47888 | 7590 | 05/19/2008 | | |
| HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 | | | EXAMINER | |
| | | | GUSOW, ANNE | |
| ART UNIT | | PAPER NUMBER | | |
| 1643 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 05/19/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. 10/522,457 | Applicant(s) FERRANDIS ET AL. |
| | Examiner ANNE M. GUSSOW | Art Unit 1643 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 August 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. Claim 6 has been amended.
2. Claims 2-6 are under examination.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Applicant has filed an English translation of the foreign priority documents as a result the priority date for the instant claims is February 26, 2002.

Specification

4. The disclosure is objected to because of the following informalities: the amendment to the specification filed March 7, 2008 contains the incorrect filing date for the PCT application PCT/FR02/00691.

Appropriate correction is required.

Objections Withdrawn

5. The objection to the specification for an incomplete description of Figure 4 is withdrawn in view of applicant's amendment to the specification.

Rejections Withdrawn

6. The rejection of claims 2-6 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 2-6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed August 23, 2007 has been carefully considered but is deemed not to be persuasive. The response does not address the written description rejection.

In response, as set forth in the previous office action on page 5, the specification as-filed does not provide adequate written description support as to the method of extraction of the 90.9 kDa protein. One of skill in the art would not be able to distinguish between the instant 90.9 kDa protein and any other 90.9 kDa protein that contains the small 6-14 amino acid peptides of SEQ ID Nos. 1-3. The claims do not provide method steps as to the extraction of the protein from the plant species. The molecular weight of a protein can change dependent upon the method of extraction.

Thus, the isolated protein is not defined. The skilled artisan cannot envision the detailed structure of the encompassed polypeptides included in a 90.9 kDa protein

comprising fragments of peptide sequences SEQ ID Nos. 1-3 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

9. The rejection of claims 2-6 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed August 23, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the isolated protein is defined as being aqueous extracted from *Pilocarpus Heterophyllus* and the protein is further identified by its molecular weight, by identification of 3 specific fragments identified by their sequence SEQ ID NO. 1, SEQ ID NO. 2 and SEQ ID NO. 3 and as being present in a glycosylated or non-glycosylated form. The specification and the claims clearly identify the protein to enable one skilled in the art to be certain to be able to obtain the same protein as described in the application. The protein does not have to be described by its exact chemical structure but only by sufficient features so one can be certain that they have the same protein as Applicants' which the present disclosure does (see response page 6).

In response to this argument, as claimed one of ordinary skill in the art would not be able to determine the 90 kDa protein isolated from *Pilocarpus Heterophyllus*. While the claim defines the aqueous extract of the plant and the molecular weight of the

Art Unit: 1643

protein, the specific characteristics of "fragments of peptide sequences SEQ ID Nos. 1-3" reads on a large number of proteins comprising only a single residue from a single peptide of SEQ ID Nos. 1-3. Thus, the protein is not specifically defined such that one of skill in the art could identify the protein for use in the method as claimed.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

May 16, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643